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Docket No. ASP-24

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

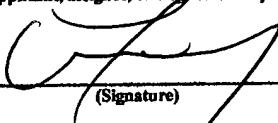
Applicants : Hui et al. Confirmation No.: 6171
Appln. No. : 09/904,667 Art Unit : 1744
Filed : July 13, 2001 Examiner : M.R. Chorbaji
Title : SURFACE TREATMENT OF ALUMINUM ALLOYS TO IMPROVE STERILIZATION PROCESS COMPATIBILITY

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Aug 16, 2004
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Andrew C. Farmer

(Name of applicant, assignee, or Registered Representative)


(Signature)

8-16-04
(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE

Dear Sir:

Presently claims 1 to 24 are pending in the application. Claims 1 to 4 and 6 to 8 stand rejected under 35 U.S.C. §103(a) over the Feldman et al. US Patent No. 5,658,529, the Green US Patent No. 3,634,937 and the Yang et al. US Patent No. 4,117,085. Claim 5 stands rejected under 35 U.S.C. §103(a) over Feldman, Green, Yang and the Alexander et al. US Patent No. 5,064,083. Claims 9 to 11, 15 to 19, 23 and 24 stand rejected under 35 U.S.C. §103(a) over Feldman and Green. Claims 12 to 14 and 20 to 22 stand rejected under 35 U.S.C. §103(a) over Feldman, Green and Alexander. Applicants respectfully traverse each of the rejections and request reconsideration and reexamination of the application.

The Examiner has rejected claims 1 to 4 and 6 to 8 as being obvious over Feldman et al., Green and Yang et al. The Examiner has further rejected claim 5 over that combination in addition with Alexander et al. However, Yang et al. is not properly within the scope and content of the prior art of Applicants' claimed invention as it is not analogous prior art. To be analogous the reference must either be in the field of Applicants' endeavor or be reasonably pertinent to a particular problem facing the inventor. MPEP §2141.01(a) Applicants' claimed invention is directed to a method of sterilizing a device, the device having aluminum oxide on its surface. The Yang et al. reference is not directed to a method of sterilization, it is in a separate field of endeavor, namely producing aluminum oxide. This is clearly a separate field of endeavor from sterilizing a device, even one having aluminum oxide thereon. Further, Yang et al. is not directly pertinent to any problem facing Applicants in the present invention. Yang et al. teach how to produce aluminum oxide without discoloring the aluminum oxide during the drying step in production. Applicants were not faced with the problem of producing aluminum oxide, in Applicants' invention the aluminum oxide is already present. Applicants are not faced with the problem of drying a slurry of aluminum oxide; in Applicants' invention there is no aluminum oxide slurry. Accordingly, Yang et al. is not analogous art and is therefore not properly within the scope and content of the prior art of Applicants' claimed invention.

Furthermore, even if Yang et al. were analogous art, the Examiner has failed to provide a suggestion for making the alleged combination with Feldman et al. and therefore has failed to establish a prima facia case of obviousness. The Examiner asserts that Yang et al. teaches values for a ratio of hydrogen peroxide to alumina and that because of this it would have been obvious to modify Feldman et al. with such a ratio to reduce discoloration of the alumina caused by high temperature. What the Examiner failed to state is that any alleged ratio taught by Yang et al. is not for use in sterilization but for drying of an alumina slurry. In Feldman et al. there is no alumina slurry and thus no reason to look to the teachings of Yang et al. Moreover, the references actually teach away from the alleged combination. Feldman et al. recognize that high concentrations of hydrogen peroxide can discolor an anodized coating and deal with finding an appropriate anodization process so that a sufficiently high concentration of hydrogen peroxide to effect sterilization can be employed without bleaching the anodization coating. Yang et al. on the other hand teach employing high quantities of hydrogen peroxide to reduce discoloration during the drying of an alumina slurry. Therefore Feldman et al. would desire lower concentrations of hydrogen peroxide to protect an anodization while Yang et al.

seek higher concentrations of hydrogen peroxide to protect alumina. These teachings are inconsistent with each other and would lead one of skill in the art away from incorporating the teachings of Yang et al. into the teachings of Feldman et al.

Even if the alleged combination were made the Examiner has not established that it would reach the claimed invention. Contrary to the Examiner's assertions Yang et al. did not teach a ratio of hydrogen peroxide to a volume of alumina but rather a ratio of hydrogen peroxide to a weight of alumina. Even if this ratio were within Applicants' claimed ratio, it is not for purposes of sterilization and thus would not occur during the sterilization process and thus would not reach that limitation of Applicants' claimed invention. Accordingly, for each of these reasons Applicants respectfully submit that the Examiner has failed to establish a prima facia case of obviousness.

The Examiner has rejected claims 9 to 11, 15 to 19, 23 and 24 over Feldman et al. and Green. Claim 9 contains the limitation of a material coated on set at least one aluminum surface, wherein said material is substantially impermeable to hydrogen peroxide gas or vapor. The alleged combination fails to teach this limitation and thus fails to establish a prima facia case of obviousness.

The Examiner has rejected claims 12 to 14 and 20 to 22 over Feldman et al., Green and Alexander et al. Alexander et al. is not analogous art. It is directed to medicine bottles having an elastomeric closure member, i.e. a rubber stopper, with the rubber stopper being coated with polyparaxylylene to prevent the stopper from contaminating the medicine. Applicants' field of endeavor is sterilization. Applicants employ hydrogen peroxide and endeavor to be compatible with a surface comprising aluminum with an aluminum oxide coating. Applicants' field of endeavor is entirely separate from Alexander et al. Furthermore, Alexander et al. do not pertain to a problem facing Applicants. Applicants' problem was determining why certain sterilization cycles failed, to which Alexander et al. are silent.

Even if Alexander et al. were properly analogous art there is no suggestion for making the alleged combination. The Examiner has failed to provide a suggestion and therefore has failed to establish a prima facia case of obviousness. The Examiner asserted that it would have been obvious to modify the method of Feldman et al. to include a polyparaxylylene coating to form a barrier between the member and the contents of the container. Reading Feldman et al. it is clear there is not need to

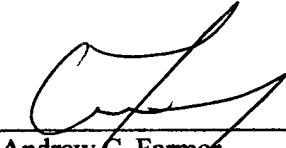
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have a barrier between the contents of the container and Feldman et al. and the aluminum surface. According one of ordinary skill in the art would not be motivated to combine Alexander et al. with Feldman et al. This suggestion is found only in Applicants' specification. Applicants found that the variation in sterilization cycle efficacy resulted from variations in the volume of aluminum oxide present in the system. Of course, it is improper to use Applicants' teachings to provide the suggestion for making the alleged combination. Further, even if made the alleged combination would not reach the claimed invention. The alleged combination created by the Examiner merely separates the contents of the container from the closure member, but does not create a barrier to any hydrogen peroxide vapor. Accordingly, the rejection is traversed.

Applicants respectfully submit that the application is presently in condition for allowance and request favorable reconsideration and early notice of allowance of the application. If it would speed prosecution, the Examiner is encouraged to contact Applicants' attorney at the telephone number listed below.

Respectfully submitted,

By:


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Dated: 8 - 16 - 04